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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,605	07/27/2001	Marcel Koken	US471	1616

7590

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Gregory B Butler  
Serono Reproductive Biology Institute  
280 Pond Street  
Randolph, MA 02368

EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/744,605

Applicant(s)

Koken

Examiner

Karen Canella

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 12-25 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

**DETAILED ACTION**

1. Please note that the examiner assigned to this application has changed.
2. Claims 16 and 18 have been amended. Claims 12-25 are pending.
3. After review and consideration of applicant's arguments regarding the disclosure of Zhu et al, the restriction requirement of Paper No 8 is withdrawn.

***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

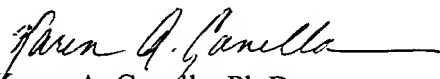
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 12-21, 24 and 25 drawn to a method of inducing the death of undesirable cells and/or a method of stimulating an immune reaction comprising the administration of a substance which promotes the targeting of the PML protein towards nuclear bodies and/or stabilization, in combination with the PML protein and/or an agent inducing the over expression of the PML protein; a method of inducing the death of undesirable cells and/or the stimulation of an immune response comprising the administration of an arsenic compound or caspase inhibitors or substrates, in combination with interferon; and a method of inducing death of undesirable cells and/or stimulation of an immune response comprising administering to a patient a caspase inhibitor and/or a caspase substrate.

Group II, claim(s) 22 and 23, drawn to pharmaceutical compositions and kits comprising caspase inhibitors and/or substrates, arsenic compounds or compounds having the same biological properties as arsenic, the PML protein, and an agent inducing the over expression of the PML protein.

5. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claims 24 and 25 have no special technical feature that define a contribution over the prior art. Claim 24 is drawn in part to a method of inducing cell death and/or stimulating an immune response comprising the administration of a caspase inhibitor to a patient. Claim 25 specifies zVad as said inhibitor. Vercammen et al (Journal of Experimental Medicine, 1998, Vol. 187, pp. 1477-1485, reference 3 of the IDS filed July 26, 2001) teach that the administration of the caspase inhibitor, z-Vad, increases the sensitivity of tumor cells to TNF-mediated necrosis (page 1479-1480). Further, Melcher et al (Nature Medicine, 1998, Vol. 4, pp. 581-587, reference 7 of the IDS filed July 26, 2001) teach that the induction of non-apoptotic, versus apoptotic, cell death in vivo results in a greater immunological reaction to the dying cells (discussion, starting on page 584). Melcher et al suggest that these findings are important for the design of therapies designed to stimulate the patient's own immune response against a tumor (page 581, second column lines 2-5). Thus, a method of treatment comprising the administration of a caspase inhibitor is obvious in light of the prior art, therefore the instant claims lack unity of invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

January 22, 2003